CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (Bos taurus and B. indicus) only.

- 1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*:
 - a) milk and milk products;
 - b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
 - c) hides and skins;
 - d) gelatin and collagen prepared exclusively from hides and skins;
 - e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;
 - f) dicalcium phosphate (with no trace of protein or fat);
 - g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which were subject to passed ante-mortem and post-mortem inspections and were not suspect or confirmed BSE cases; and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;
 - h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.
- 2. When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the *exporting country, zone* or *compartment*.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 2.3.13.2.

The BSE risk status of the cattle population of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* (which is reviewed annually), based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective:

a) Release assessment

Release assessment consists of assessing the likelihood that the BSE a transmissible spongiform encephalopathy (TSE) agent has been introduced into the cattle population from a pre-existing agent TSE in the indigenous ruminant population or via commodities potentially contaminated with the BSE a TSE agent, through a consideration of the following:

- i) the presence or absence of animal TSE agents the BSE agent in the country, zone or compartment and, if present, evidence regarding their its prevalence based on the outcomes of surveillance;
- ii) meat-and-bone meal or greaves from the indigenous ruminant population;
- iii) imported meat-and-bone meal or greaves;
- iv) imported live ruminants animals;
- v) imported animal feed and feed ingredients;
- vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. and may have been fed to cattle;
- vii) imported products of ruminant origin for in vivo use in cattle.

The results of any surveillance and other epidemiological investigation into the disposition of the commodities identified above (especially surveillance for BSE conducted on the eattle population) relevant to the above should be taken into account in carrying out the assessment.

b) Exposure assessment

If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

- i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

- the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;
- iv) the level of surveillance for BSE conducted on the cattle population to that time and the results of that surveillance;
- 2. on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Appendix 3.8.4.;
- 3. the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;
- 4. the examination in an *approved laboratory* of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

When the *risk assessment* (which takes into account the surveillance referred to in the release and exposure assessments above) demonstrates negligible risk, the country should conduct Type B surveillance in accordance with Appendix 3.8.4.

When the *risk assessment* (which takes into account the surveillance referred to in the release and exposure assessments above) demonstrates non-negligible fails to demonstrate negligible risk, the country should conduct Type A surveillance in accordance with Appendix 3.8.4.

Article 2.3.13.3.

Negligible BSE risk

Commodities from the cattle population of a country, zone or compartment pose a negligible risk of transmitting the BSE agent, should the following conditions be met:

- 1. a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate generic specific measures have been taken for the relevant period of time defined below to manage all risks each risk identified;
- 2. the country has demonstrated that Type B surveillance, in accordance with Appendix 3.8.4, is in place and the relevant points target, in accordance with Table 1, has been met;

3. EITHER:

- a) there has been no *case* of BSE, or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and:
 - i) the criteria in points 2) to 4) of Article 2.3.13.2. have been complied with for at least 7 years; and
 - ii) it has been demonstrated, through an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* or *greaves* derived from ruminants has not been fed to

ruminants;

OR

- b) the last indigenous case of BSE was reported more than 7 years ago any indigenous case of BSE was born more than 8 years ago; and
 - i) the criteria in points 2) to 4) of Article 2.3.13.2. have been complied with for at least 7 years; and
 - ii) it has been demonstrated, thorough an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants; and
 - iii) all BSE cases, as well as:
 - all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and
 - all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
 - if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 2.3.13.4.

Controlled BSE risk

Commodities from the cattle population of a country, zone or compartment pose a controlled risk of transmitting the BSE agent, should the following conditions be met:

- 1. a *risk assessment*, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate measures are being taken, but have not been taken for the relevant period of time to manage all risks identified the country has not demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage all risks identified;
- 2. the country has demonstrated that Type A surveillance in accordance with Appendix 3.8.4. is in place; Type B surveillance may replace Type A surveillance once the relevant points target, in accordance with Table 1, is met;

3. EITHER

a) there has been no case of BSE or any case of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2) to 4) of

Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit, that *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants, but at least one of the following two conditions applies:

- i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;
- ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

OR

- b) there has been an indigenous *case* of BSE reported, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit that *meat-and-bone meal* and *greaves* derived from ruminants have not been fed to ruminants, but at least one of the following two conditions applies:
 - i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;
 - ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* and *greaves* derived from ruminants to ruminants have been in place for 8 years;

AND

- iii) all BSE cases, as well as:
 - all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and
 - all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
 - if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 2.3.13.5.

Undetermined BSE risk

The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 2.3.13.6.

When importing from a country, zone or compartment posing a negligible BSE risk, Veterinary

Administrations should require:

for all commodities from cattle not listed in point 1) of Article 2.3.13.1.

the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.

Article 2.3.13.7.

When importing from a country, zone or compartment posing a controlled BSE risk, Veterinary Administrations should require:

for cattle

the presentation of an international veterinary certificate attesting that:

- 1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.;
- 2. cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3) b) iii) of Article 2.3.13.4.;
- 3. in the case of a country, *zone* or *compartment* with an indigenous *case*, cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 2.3.13.8.

When importing from a country, zone or compartment with an undetermined BSE risk, Veterinary Administrations should require:

for cattle

the presentation of an international veterinary certificate attesting that:

- 1. the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 2. all BSE *cases*, as well as:
 - a) all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and
 - b) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE cases,

if alive in the country, zone or compartment, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;

- 3. cattle selected for export:
 - a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;
 - b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 2.3.13.9.

When importing from a country, zone or compartment posing a negligible BSE risk, Veterinary Administrations should require:

for fresh meat and meat products from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an international veterinary certificate attesting that:

- 1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.;
- 2. <u>the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* originate.</u>

Article 2.3.13.10.

When importing from a country, zone or compartment posing a controlled BSE risk, Veterinary Administrations should require:

for fresh meat and meat products from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an international veterinary certificate attesting that:

- 1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.;
- 2. <u>the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and postmortem inspections ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* and *meat products* originate;</u>
- 3. cattle from which the *fresh meat* and *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
- 4. the *fresh meat* and *meat products* do not contain were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - a) the tissues listed in Article 2.3.13.13.,
 - b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age,

all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.

Article 2.3.13.11.

When importing from a country, zone or compartment with an undetermined BSE risk, Veterinary Administrations should require:

for fresh meat and meat products from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an international veterinary certificate attesting that:

- 1. the cattle from which the *fresh meat* and *meat products* originate:
 - a) are not suspect or confirmed BSE cases;
 - b) have not been fed meat-and-bone meal or greaves derived from ruminants;
 - c) were subjected to passed ante-mortem and post-mortem inspections;
 - d) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
- 2. the *fresh meat* and *meat products* do not contain were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - a) the tissues listed in Article 2.3.13.13.,
 - b) nervous and lymphatic tissues exposed during the deboning process,
 - c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age,

all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.

Article 2.3.13.12.

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5. should not be traded between countries.

Article 2.3.13.13.

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

- 2. From cattle that were at the time of slaughter over 30 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.
- 3. From cattle that were at the time of slaughter over 12 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.14.

Veterinary Administrations of importing countries should require:

for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an international veterinary certificate attesting that the commodities came from:

- 1. a country, zone or compartment posing a negligible BSE risk; or
- 2. a country, zone or compartment posing a controlled BSE risk; and
 - a) skulls and vertebrae (except tail vertebrae) have been excluded;
 - b) the bones have been subjected to a process which includes all the following steps:
 - i) pressure washing (degreasing),
 - ii) acid demineralisation,
 - iii) prolonged alkaline treatment,
 - iv) filtration,
 - v) sterilisation at $\geq 138^{\circ}$ C for a minimum of 4 seconds,

or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.15.

Veterinary Administrations of importing countries should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an international veterinary certificate attesting that it originates from:

- 1. a country, zone or compartment posing a negligible BSE risk; or
- 2. a country, *zone* or *compartment* posing a controlled BSE risk, and it originates from cattle which have been subjected to <u>passed</u> ante-mortem and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 2.3.13.13.

Article 2.3.13.16.

Veterinary Administrations of importing countries should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an international veterinary certificate attesting that:

- 1. they originate from a country, zone or compartment posing a negligible BSE risk; or
- 2. they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

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